

What is claimed is:

1. An orthopedic implant comprising an interpositional arthroplasty implant adapted to be positioned within an orthopedic joint in order to provide an improved combination of wear resistance, congruence, and cushioning.
- 5 2. An implant according to claim 1 wherein the implant comprises an interpositional arthroplasty implant for insertion into a knee joint.
3. An implant according to claim 2 wherein the implant comprises a plurality of biomaterials, including a first biomaterial providing a first surface for use in apposition to femoral bone, and a second biomaterial providing a second surface  
10 for use in apposition to tibial bone, wherein the first biomaterial provides improved wear resistance as compared to the second biomaterial and the second biomaterial provides improved congruence and cushioning as compared to the first biomaterial.
4. An implant according to claim 3 wherein the first and second biomaterials each comprise polymeric biomaterials; wherein the biomaterials each  
15 meets or exceeds the requirements of ISO 10993 with respect to cytotoxicity, sensitization, genotoxicity, chronic toxicity, and carcinogenicity.
5. An implant according to claim 4 wherein the first and second polymeric biomaterials are independently selected from the group consisting of polyurethanes having different physical properties.
- 20 6. An implant according to claim 5 wherein the first and second polymeric biomaterials independently comprise polyurethane compositions having respective wear resistance, congruency and cushioning properties.
7. An implant according to claim 6 wherein the implant has a substantially kidney bean shape in plan and includes at least one tibial projection.
- 25 8. An implant according to claim 7 wherein the first surface is generally concave and the second surface is generally convex.
9. An implant according to claim 2 wherein the implant comprises a single polymeric biomaterial having an improved combination of wear resistance, congruence and cushioning, in order to provide both a first surface for use in  
30 apposition to femoral bone and a second surface for use in apposition to tibial bone.
10. An implant according to claim 3 wherein the first biomaterial and the second biomaterial are mechanically interlocked with one another.

11. An implant according to claim 10 wherein one of the parts defines at least one recess and the other of the parts defines a protrusion disposed within the recess.

5 12. An implant according to claim 10 wherein the first biomaterial and the second biomaterial meet one another at an interface, and at least one of the parts includes at least one protrusion extending beyond the interface.

13. An implant according to claim 12 wherein an enlarged portion of the protrusion is disposed on a second side of the interface and a body portion of the at least one part is disposed on a first side of the interface.

10 14. An implant according to claim 3 wherein the first biomaterial comprises a polyurethane having a Shore hardness of at least about 60 D or more, and the second biomaterial comprises a polyurethane having a Shore hardness of at least about 60 D or less.

15 15. An implant according to claim 14 wherein the first and second polymeric biomaterials are biocompatible with respect to cytotoxicity, sensitization, genotoxicity, chronic toxicity, and carcinogenicity.

16 16. An implant according to claim 15 wherein the first and second biocompatible polymeric biomaterials independently comprise polyurethane compositions.

20 17. An implant according to claim 16 wherein the first biocompatible polyurethane has a Shore hardness of at least 60 D or more, and the second biocompatible polyurethane has a Shore hardness of at least 60 D or less.

25 18. An interpositional arthroplasty implant adapted for insertion into a knee in order to provide an improved combination of wear resistance, congruence, and cushioning comprising an implant having a plurality of biomaterials, including a first biomaterial providing a first surface for use in apposition to femoral bone, and a second biomaterial providing a second surface for use in apposition to tibial bone, wherein the first biomaterial provides improved wear resistance as compared to the second biomaterial and the second biomaterial provides improved congruence and  
30 cushioning as compared to the first biomaterial, wherein the first and second biomaterials are independently selected from the group consisting of polyurethanes having different physical properties.

19. An implant according to claim 18 wherein the first and second polyurethanes are biocompatible with respect to cytotoxicity, sensitization, genotoxicity, chronic toxicity, and carcinogenicity.

20. An implant according to claim 19 wherein the implant has a substantially kidney bean shape in plan and includes at least one tibial projection.

21. An implant according to claim 20 wherein the first surface is generally concave and the second surface is generally convex.

22. An implant according to claim 19 wherein the first biocompatible polyurethane has a Shore hardness of at least about 60 D or more, and the second biocompatible polyurethane has a Shore hardness of at least about 60 D or less.

23. An implant according to claim 18 wherein the implant hydrates less than about two percent of its weight in vivo.

24. An implant according to claim 18 wherein the interface between the first and second biomaterials has a greater tear strength than the first and second biomaterials.

25. An orthopedic implant for a joint comprising:  
a first side sized and shaped for contacting a first surface of said joint;  
a second side sized and shaped for contacting a second surface of said joint;  
said first and second sides integrally connected to each other to form said implant;  
and,

said first side having a greater wear resistance than said second side.

26. An implant according to claim 25, wherein said second side includes greater congruence properties than said first side.

27. An implant according to claim 25, wherein said second side includes greater cushioning properties than said first side.

28. An implant according to claim 25, wherein said first surface of said joint is a surface of a femoral bone.

29. An implant according to claim 28, wherein said second surface of said joint is a surface of a tibial bone.

30. An implant according to claim 25, wherein said wear resistance of said first side includes an abrasion property equal to DIN abrasion value of less than about 50 cubic mm.

5 31. An implant according to claim 25, wherein said wear resistance of said first side includes a hardness property equal to a Shore hardness of greater than about 60 D.

32. An implant according to claim 26, wherein said congruence property of said second side includes a compressive modulus property and a hardness property that are each less than a compressive modulus property and a hardness property of  
10 said first side, respectively.

33. An implant according to claim 32, wherein said compressive modulus property and said hardness property of said second side is less than about 5000 psi wet and less than about 60 Shore D, respectively.

34. An implant according to claim 27, wherein said cushioning property of  
15 said second side includes a compressive modulus property, a hardness property and a tensile modulus property that are each less than a compressive modulus property, a hardness property and a tensile modulus property of said first side.

35. An implant according to claim 34, wherein said compressive modulus property, said hardness property and said tensile modulus property of said second side  
20 is less than about 5000 psi wet, less than about 60 Shore D and less than about 3000 psi dry and 1920 psi wet, respectively.

36. An implant according to claim 25, wherein said first side of said implant is a first biomaterial and said second side of said implant is a second biomaterial, said first biomaterial being different than said second biomaterial.

25 37. An implant according to claim 36, wherein said first and second biomaterials are each polyurethanes.

38. A method of treating a joint comprising:  
identifying a joint, said joint having opposing first and second surfaces;  
preparing said joint for said treatment;  
30 inserting at least one substance between said first and second surfaces;  
securing said at least one substance between said first and second surfaces  
such that under normal functioning of said joint, resistance to wear of said joint

occurs primarily between said first surface and said substance and such that cushioning and congruency of said joint occurs primarily between said second surface and said substance.

39. A method according to claim 38, wherein the resistance to wear  
5 occurring primarily between said first surface and said at least one substance includes said first surface contacting a substance having a shore hardness of greater than about 60 Shore D and said second surface contacting a substance having a shore hardness of less than about 60 Shore D.

40. A method according to claim 38, wherein the resistance to wear  
10 occurring primarily between said first surface and said at least one substance includes said first surface contacting a substance have a DIN abrasion value of less than about 50 cubic mm and a second surface contacting a substance having a DIN abrasion value of greater than about 50 cubic mm.

41. A method according to claim 38 said first surface contacting a  
15 substance having a shore hardness of greater than about 60 Shore D and said second surface contacting a substance having a shore hardness of less than about 60 Shore D.

42. An orthopedic implant comprising an interpositional arthroplasty  
implant adapted to be positioned within an orthopedic joint in order to provide an improved combination of wear resistance, congruence, and cushioning, wherein the  
20 implant includes a polyurethane, and further wherein the urethane is loaded with a drug that can be eluted over time into the surrounding joint or bone.

43. An orthopedic implant according to claim 42, wherein the implant has one or more reservoirs for antibiotic placement.

44. A drug reservoir for use in a implantable or transdermal implantable  
25 device comprising a layer of a polyurethane formed by preferential swelling of a bulk polymeric layer.

45. A drug reservoir according to claim 44, wherein the drug reservoir serves a secondary function in the body.

46. A drug reservoir according to claim 45, wherein the reservoir is formed  
30 by swelling the polymer with an organic or water based solvent.

47. A tissue bulking agent comprising an injectable biocompatible suspension of polyurethane particles.

48. A tissue bulking agent according to claim 47 wherein the particles are between 10 microns and 100 microns, in their largest dimension.

49. A tissue bulking agent according to claim 48, wherein the suspension media is a biocompatible fluid or gel.

5 50. A tissue bulking agent according to claim 49 wherein the fluid or gel comprises hyaluronic acid.

51. A polymeric interpositional arthroplasty implant adapted to be positioned in the acetabulum to provide a wear and load bearing surface in a hip joint.

10 52. An implant as in claim 51 wherein the device has the configuration resembling the acetabulum to fit between the acetabulum and the femoral head.

53. An implant as in claim 51 wherein the implant contains a major load bearing area and a non-major load bearing area, wherein the major load bearing area comprises a high durometer, wear resistant polyurethane and the non-major load bearing area comprises a softer durometer, more compliant polyurethane.

15 54. An implant as in claim 53 wherein the compliant portion of the implant allows the implant to be folded for insertion through a minimally invasive surgical incision.

55. A method for predicting wear from compositional data, comprising measuring the content of T2000, BDO, and T1000 in a polymer and determining the  
20 predicted wear by manipulating the contents by experimental coefficients.

56. A method for predicting wear from tensile data comprising measuring a the modulus at yield, elongation and strain at yield of a polymer and determining predicted wear by manipulation of the data by experimental coefficients.